UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE ACTOS DIRECT PURCHASER ANTITRUST LITIGATION THIS DOCUMENT RELATES TO: ALL ACTIONS	Master File No. 1:15-cv-3278-RA-RLE

MEMORANDUM IN SUPPORT OF
DEFENDANTS' JOINT MOTION TO DISMISS

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INTRODUCTION

The Direct Purchaser Plaintiffs ("Plaintiffs") challenge the same provisions of the same settlement agreements under the same legal theories that the Court rejected in *In re Actos End Payor Antitrust Litigation*, No. 13-cv-9244, 2015 WL 5610752 (S.D.N.Y. Sept. 22, 2015). Plaintiffs have had the advantage of drafting behind the *End Payor* plaintiffs, filing their complaint after motions to dismiss were fully briefed and argued in the *End Payor* case, and then amending their complaint after this Court's decision in *End Payor*. Dkt. 55, Second Consolidated Complaint ("Am. Compl."). It is now clear that even with this advantage, Plaintiffs have been unable to cure any of the fundamental legal defects that led to the Court's *End Payor* decision. The current complaint has pages of rhetoric, colorful terminology, and speculation. But these add nothing to the same facts and legal claims that were dismissed in *End Payor*, and they do not change the settlement agreements, which were found not to give rise to an antitrust claim. *See Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (surviving Rule 12(b)(6) dismissal "requires more than labels and conclusions"); *Papasan v. Allain*, 478 U.S. 265, 286 (1986) (on a motion to dismiss, courts "are not bound to accept as true a legal conclusion couched as a factual allegation").

In the *End Payor* case, the Court held that the same settlement agreements challenged by Plaintiffs here (1) involved no payments from Takeda to any Generic Defendant, (2) simply granted a compromise date of generic entry, permitting the Generic Defendants to compete with versions of ACTOS and ACTO*plus* met more than three years earlier than if they had litigated their patent cases and lost, and (3) amounted to nothing more than parallel conduct consistent with each Generic Defendant's independent self-interest. There are no allegations in Plaintiffs' Amended Complaint justifying a different result in this case.

First, Plaintiffs' challenges to the settlement agreements allege the very same imagined "payments" as the plaintiffs in *End Payor*: accelerated-entry provisions (which Plaintiffs rename "coordination clauses"), licenses for Teva to sell competing products covered by the same patents, and licenses for Actavis and Ranbaxy to also sell competing products covered by the same patents (called "sweetheart deals" in the *End Payor* case and "higher-than-market side deals" by these Plaintiffs). In *End Payor*, the Court rejected the argument that the accelerated-entry provisions and the license terms were "reverse payments." The Court held instead that they were lawful and procompetitive ways to settle patent litigation and shielded from antitrust scrutiny by *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013). The underlying operative facts—the terms of the settlement agreements—have not changed between the *End Payor* case and this one, and neither should the outcome.

Second, Plaintiffs allege no more plausible a theory of causation than the *End Payor* plaintiffs. Plaintiffs allege that entry by the Generic Defendants would have occurred earlier because either (1) the Generic Defendants would have won the underlying patent infringement cases, or (2) the supposed weakness of the patent claims would have led to settlements with earlier generic entry dates. The Court rejected the former theory in *End Payor* as unduly speculative. The latter theory is even less grounded on well-pled facts than the former, as it is predicated not only on speculation that the Generic Defendants would have won, but also on speculation that all the parties knew so and agreed so at the time, topped with even more speculation that the parties actually would have reached settlements on the terms Plaintiffs say they should have reached. Courts have long rejected claims based on such speculation. Furthermore, to the extent Plaintiffs argue that the Defendants' agreements were not competitive

enough, such an argument has been squarely rejected by the courts (including this one). *See, e.g.*, *Actavis*, 133 S. Ct. at 2234; *End Payor*, 2015 WL 5610752, at *29.

Third, Plaintiffs here come no closer to alleging an illegal conspiracy than the *End Payor* plaintiffs. Plaintiffs do not allege any facts indicating coordinated conduct among the Defendants. All they do is re-assert the same implausible theory from the *End Payor* case that Takeda's patent infringement lawsuits were likely to lose and so no first-filer Generic Defendant would have settled absent assurances that all first filers would have done the same. Not only does this theory depend on speculative assumptions, but it ignores that each settlement served each Generic Defendant's independent self-interest, by bringing "an end to costly litigation" and assuring "that each Generic Defendant would not be disadvantaged regarding [generic entry]" by inclusion of the accelerated-entry clause. *End Payor*, 2015 WL 5610752, at *25 (alteration in original) (quoting *King Drug Co. of Florence v. Cephalon, Inc.*, 2014 WL 2813312, at *12 (E.D. Pa. June 23, 2014)). Moreover, "[t]he practical effect of the acceleration clauses was . . . to increase competition in the event that other generics entered the market earlier than contemplated by the agreement." *Id.* at *15. The Court correctly rejected the same conspiracy theories in the *End Payor* case and should do so again here.

Plaintiffs fail to allege facts warranting a different result than in the *End Payor* case, and their Amended Complaint likewise should be dismissed. Given the numerous opportunities Plaintiffs have already had to state a valid claim, the Amended Complaint should be dismissed with prejudice.

BACKGROUND

Putting aside rhetoric and legal argument, the *facts* alleged by the Plaintiffs here relating to the ACTOS and ACTO*plus* met patent litigations and patent settlements are no different from those alleged by the *End Payor* plaintiffs and described in the Court's prior opinion. *See End*

Payor, 2015 WL 5610752, at *4-9. We summarize those facts below with citations to the corresponding paragraphs in Plaintiffs' current complaint.

I. ACTOS Litigation and Settlements

In January 1999, Takeda submitted an NDA seeking approval to market a drug called ACTOS (active ingredient pioglitazone hydrochloride) designed to treat Type 2 diabetes in adults. Am. Compl. ¶ 159. The FDA approved the application in July 1999, and pursuant to the Hatch-Waxman Act, Takeda listed numerous patents as claiming the drug. *Id.* ¶¶ 160, 161, 178. One patent claims the active ingredient, pioglitazone hydrochloride: U.S. Patent No. 4,687,777 ("'777 patent"), which expired in January 2011. *Id.* ¶ 158. Two patents claim methods of using pioglitazone hydrochloride in combination with other medications and also compositions combining it with other medications: U.S. Patent Nos. 5,965,584 ("'584 patent") and 6,329,404 ("'404 patent"), both of which expire in June 2016. *Id.* ¶¶ 166, 172. Eight additional patents claim various methods of using ACTOS with other drug products to treat particular conditions or side effects ("method-of-use-only patents"). *Id.* ¶ 178.

In July 2003, three generic manufacturers—Actavis, Mylan, and Ranbaxy—filed ANDAs seeking FDA approval to market generic versions of ACTOS. *Id.* ¶ 189. Each filed a paragraph IV certification as to the '584 and '404 patents and ultimately section viii statements as to the patents listed in the Orange Book that had only method-of-use claims. *Id.* ¶¶ 191-196. Mylan also made a paragraph IV certification as to the '777 patent (challenging the validity or infringement of that patent), whereas Actavis and Ranbaxy each made a paragraph III certification as to the '777 patent (indicating they would not seek final FDA approval until the expiration of that patent). *Id.*

In July 2004, a year after the first ANDAs were filed, Teva submitted its own ANDA seeking to market a generic ACTOS product. *Id.* ¶ 204. As such, Teva was not a "first filer" for

generic ACTOS and could not come to market with product it manufactured under its ANDA until at least 180 days after the first filers. Another generic company, Alphapharm (since acquired by Mylan, *see id.* ¶ 189) made a paragraph IV certification as to only the ’777 patent.

Takeda filed patent infringement suits against each generic applicant in this Court. *Id.* ¶¶ 198, 224. The cases were assigned to Judge Cote, who first considered whether Mylan and Alphapharm had infringed Takeda’s ’777 patent. In 2006, Judge Cote found the patent valid and infringed, awarded Takeda more than $16.8 million in attorneys’ fees, and entered a limited final judgment under Rule 54(b). The Federal Circuit affirmed both the infringement finding and fee awards. *Takeda Chem. Indus., Ltd. v. Mylan Labs., Inc.*, 417 F. Supp. 2d 341, 398 (S.D.N.Y. 2006), *aff’d*, 492 F.3d 1350 (Fed. Cir. 2007); *Takeda Chem. Indus., Ltd. v. Mylan Labs., Inc.*, 459 F. Supp. 2d 227 (S.D.N.Y. 2006), *aff’d*, 549 F.3d 1381 (Fed. Cir. 2008).

Back before the district court, the parties engaged in extensive discovery and motion practice in advance of a trial on the remaining claims related to the ’584, ’404, and method-of-use-only patents that claimed pioglitazone hydrochloride together with other drugs. *See End Payor*, 2015 WL 5610752, at *5-6. Judge Cote held that the generic products could infringe the ’584, ’404, and other method-of-use patents under an inducement theory even if the generic products contained only pioglitazone hydrochloride. *Id.* at *23 (quoting *Takeda Pharms. Co. v. Sandoz, Inc.*, 2007 WL 2936208, at *5 (S.D.N.Y. Oct. 9, 2007) (rejecting argument “that a generic drug manufacturer cannot induce infringement of combination-use patents”)).

In March 2010, to resolve this protracted litigation, Takeda entered into individual settlement agreements to end the litigations over ACTOS with each of three generic companies: Actavis, Mylan, and Ranbaxy. Am. Compl. ¶ 248. Takeda made no payment whatsoever to any of them as part of the settlements, or otherwise. *See End Payor*, 2015 WL 5610752, at *14-18.

Rather, Takeda granted each generic company "a royalty-free, nonexclusive" license to make and sell a generic version of ACTOS before the expiration of Takeda's patents. Ex. 1, § 3.1; Ex. 2, § 3.1; Ex. 4, § 3.1.[1] Takeda granted each generic company the right to come to market with a generic ACTOS product at the earlier of (i) August 17, 2012 (more than three years before the expiration of the patents at issue) or (ii) when another generic version of ACTOS came to market. As the first filers to challenge the patents listed for ACTOS, these three generic companies would share 180 days of marketing exclusivity. Their ability to accelerate the generic entry date if any other generic version of ACTOS was introduced preserved part of their first-filer rights. *End Payor*, 2015 WL 5610752, at *14.

The settlements thus guaranteed generic entry of ACTOS at least three years before the '584 and '404 patents were set to expire, if not earlier. Takeda also granted Ranbaxy an option to distribute Takeda-manufactured ACTOS tablets under Ranbaxy's label (an "authorized generic") in the event that Ranbaxy was unable to manufacture generic ACTOS itself. Ex. 1, § 3.6 & Ex. B. Ranbaxy ultimately invoked this option, which allowed it to sell a competing ACTOS product when it otherwise would have been unable to do so. Ranbaxy paid Takeda a portion of its gross profits on these sales. Ex. 1, § 3.6 & Ex. B.

The settlement agreements with Ranbaxy and Actavis also licensed Ranbaxy and Actavis to sell, beginning in 2015, a competing version of "ACTO*plus* met," which is covered by the same patents as ACTOS, that those companies otherwise might not have been able to sell. *See id*. § 3.2; Ex. 4, § 3.2. Ranbaxy never filed an ANDA for generic ACTO*plus* met, and Actavis

[1] The settlement agreements at issue are attached as Exhibits 1-5 to the January 25, 2016 Declaration of George Kokkines, which Defendants have served on Plaintiffs and have sought permission to file under seal: Exhibit 1 (Ranbaxy), Exhibits 2-3 (Mylan), Exhibit 4 (Actavis), and Exhibit 5 (Teva). These agreements may be considered on a motion to dismiss. *End Payor*, 2015 WL 5610752, at *1 n.3 (citing *In re Thelen LLP*, 736 F.3d 213, 219 (2d Cir. 2013)).

never received FDA approval for ACTO*plus* met. Thus, neither ultimately launched a generic version of that product.

Takeda did not agree to limit competition for generic ACTOS. To the contrary, the settlements expressly contemplated that Takeda could license an "authorized generic" version of ACTOS, as it did with Ranbaxy, and that Takeda had the option to license other generic companies to introduce their own generic ACTOS products.

After months of further litigation with additional generic applicants, in December 2010, Takeda also settled its ACTOS dispute with Teva. Am. Compl. ¶ 295. Takeda licensed Teva to sell Takeda-manufactured tablets under Teva's label (another "authorized generic") starting no later than August 17, 2012. Ex. 5, §§ 3.1, 3.2. Takeda made no payment to Teva under the settlement or otherwise. On the contrary, as in a traditional patent settlement, Teva (the alleged patent infringer) agreed to pay Takeda (the patent holder) "a royalty of seventy five percent (75%)" of its net profit on any authorized generic sales during the initial 180-day marketing period. *Id.* § 3.1 & Ex. B at 3. Takeda also granted Teva a nonexclusive, royalty-free license to market its own generic version of ACTOS after the 180-day exclusivity period enjoyed by the first filers. *Id.* § 3.3.

As required, each of these settlements was submitted to the FTC and DOJ for review. *See* Ex. 1, § 2.6; Ex. 2, § 2.6; Ex. 4, § 2.6; Ex. 5, § 2.9. The government did not investigate or object.

II. ACTO*plus* met Litigation and Settlements

Takeda also submitted an NDA for a related product called ACTO*plus* met, which combined pioglitazone hydrochloride and metformin hydrochloride. *See* Am. Compl. ¶ 214. The FDA approved the new drug in August 2005, and Takeda listed the '584 patent (and other

method-of-use patents, all of which were also listed in connection with ACTOS) in the Orange Book as claiming the drug. *Id.* ¶ 215.

In March 2008, Mylan filed an ANDA seeking approval to market a generic version of ACTO*plus* met and included a paragraph IV certification as to the '584 patent. *See id.* ¶ 217. Takeda initiated patent-infringement litigation against Mylan, *id.* ¶ 219, which again involved extensive discovery. Two years later, in March 2010, Takeda settled the ACTO*plus* met litigation with Mylan. *Id.* ¶¶ 254-255. Once again, Takeda made no payments to Mylan under the settlement agreement or otherwise. Instead, Takeda granted Mylan "a non-exclusive, royalty-free" license to make and sell a generic version of ACTO*plus* met at the earlier of December 14, 2012, the date on which another generic ACTO*plus* met product was introduced, or the date on which the average monthly U.S. total prescription volume for ACTO*plus* met dropped below a certain threshold. Ex. 3, § 3.1. Because Mylan was the "first filer" for ACTO*plus* met, it was entitled to 180 days of exclusivity pursuant to the Hatch-Waxman Act. This acceleration provision, combined with the declining-sales provision, ensured that Mylan could enjoy benefits of its first-filer status, in a manner that would be shared by consumers as well.

In December 2008, Teva submitted an ANDA for a generic version of ACTO*plus* met and filed paragraph IV certifications as to the '584 patent and two other Takeda patents. *See* Am. Compl. ¶ 222. Takeda filed suit against Teva for infringement of these patents. *Id.* ¶ 224. Takeda ultimately settled this litigation with Teva over ACTO*plus* met in the same settlement agreement that resolved the two companies' ACTOS litigation. *Id.* ¶ 295. Takeda made no payment at all to Teva. Once again, Takeda granted Teva a license to market Takeda's authorized generic version of ACTO*plus* met, and the license began no later than December 14,

2012, or even earlier in certain circumstances. Ex. 5, §§ 3.4, 3.5. The agreement thus guaranteed there would be additional generic competition for ACTO*plus* met during Mylan's otherwise exclusive marketing period. *End Payor*, 2015 WL 5610752, at *17. As with the ACTOS settlements, far from a *reverse* payment from Takeda to Teva, Teva agreed to pay Takeda "a royalty of seventy five percent (75%)" of its net profit on any authorized generic sales of ACTO*plus* met during the first 180 days. Ex. 5, § 3.3 & Ex. B at 3. And Takeda granted Teva a nonexclusive, royalty-free license to market its own generic version of ACTO*plus* met after the 180-day period of exclusivity. *Id.* § 3.6.

Takeda, Mylan, and Teva submitted their individual agreements to the government for review. *See* Ex. 3, § 2.6; Ex. 5, § 2.9. Once again, neither the FTC nor the DOJ objected to their terms or raised any antitrust concerns.

In August 2012, Mylan launched its generic version of ACTO*plus* met, and Teva later launched the Takeda "authorized generic" version of the drug.[2]

III. Antitrust Challenges to the Settlement Agreements

In a 52-page opinion issued on September 22, 2015, this Court held in *End Payor* that these same settlement agreements did not violate the antitrust laws. The Court held that they (1) "simply granted the Generic Defendants a compromise date of generic entry—the very type of settlement sanctioned by the [Supreme Court in] *Actavis*"; (2) permitted entry of "a generic ACTOS product . . . almost four years prior to the expiration" of the asserted patents, and permitted entry of a generic ACTO*plus* met product near the same time; (3) were not accompanied by any "'plus factors'" that might "support an inference that any of the Defendants unlawfully agreed to coordinate their settlements"; and (4) could not have caused any

[2] The entry occurred several months before December 14, 2012, because certain market conditions defined in the settlement agreement occurred. *See* Ex. 3, § 3.1(a), (f).

competitive harm unless one were to make "unduly speculative" assumptions that "Takeda's patent claims were invalid and the infringement actions against the [Generic] Defendants would have failed." *End Payor*, 2015 WL 5610752, at *6 & n.6, *14, *24, *27.

The Court reached these holdings under the same federal legal standards applicable to this case. *Id.* at *10, *23.

ARGUMENT

I. Because the Settlement Agreements Involve Only Early-Entry Licenses, They Do Not Give Rise to Antitrust Claims (Counts 4, 5, 6, 8)

Before a settlement of Hatch-Waxman patent litigation can be subject to antitrust scrutiny, Plaintiffs must allege that "the settlement term at issue" is "(1) a 'payment' that is (2) made in 'reverse'—that is, from the patent holder to the alleged infringer—and is (3) 'large,' and (4) 'unexplained.'" *End Payor*, 2015 WL 5610752, at *11. The only purported reverse payments that Plaintiffs allege here, however, are the same procompetitive licensing terms that the Court addressed in *End Payor* and held were not reverse payments as a matter of law.

A. The Settlement Agreements Provide Only Lawful and Procompetitive Early-Entry Licenses to the Generic Defendants

Under the plain terms of each challenged settlement, each Generic Defendant received an early-entry license from Takeda. Ex. 1, § 3.1; Ex. 2, § 3.1; Ex. 3, § 3.1; Ex. 4, § 3.1; Ex. 5, §§ 3.1, 3.4. None of the settlements involved Takeda making any payment, much less large or unexplained payments. *End Payor*, 2015 WL 5610752, at *15.[3] Rather, each settlement allowed a Generic Defendant to enter the market more than three years before Takeda's patents were set to expire. For ACTOS, "[p]ursuant to the essential terms of the settlement agreements with Mylan, Ranbaxy, and Actavis, Takeda licensed the[se] Generic Defendants to enter the market

[3] To the contrary, two of the agreements—one with Ranbaxy and one with Teva—provided for the settling Generic Defendant to make payments to Takeda. Ex. 1, § 3.6 & Ex. B; Ex. 5, § 3.3 & Ex. B.

on August 17, 2012," with even earlier generic entry in some circumstances. *Id.* at *14. For ACTO*plus* met, Takeda granted Mylan "a license to enter that market no later than December 14, 2012," again permitting earlier entry in some circumstances, which occurred, enabling Mylan to enter in August 2012. *Id.* at *6 n.6; *see also* Ex. 3, § 3.1(a), (f). Takeda also "granted Teva licenses to launch authorized generic versions of ACTOS and ACTO*plus* during the first 180 days of generic marketing," and granted Ranbaxy a license to market an authorized generic version of ACTOS. *End Payor*, 2015 WL 5610752, at *8; Ex. 1, § 3.6 & Ex. B. "At their core, the settlements at issue simply granted the Generic Defendants a compromise date of generic entry-the very type of settlement sanctioned by the [Supreme Court in] *Actavis* . . . ." *End Payor*, 2015 WL 5610752, at *14.

This conclusion is not changed by Plaintiffs' peculiar rhetoric that the settlements "were not 'licenses' at all" but "are instead better characterized as anti-licenses" that "simply reach[ed] a covenant not to sue." *See* Am. Compl. ¶ 275. That is just wordplay. The settlements granted express *licenses* by their clear terms. *See* Ex. 1, § 3.1 ("Takeda hereby grants to Ranbaxy and its Affiliates a non-exclusive . . . and non-assignable license under the Licensed Patents to import, manufacture, offer for sale, sell and distribute the Ranbaxy ANDA Product"); Ex. 2, § 3.1; Ex. 3, § 3.1; Ex. 4, § 3.1; Ex. 5, §§ 3.3, 3.6. Plaintiffs' rhetoric is thus refuted by the agreements' plain language. *See Rapoport v. Asia Elecs. Holding Co.*, 88 F. Supp. 2d 179, 184 (S.D.N.Y. 2000) ("If [incorporated] documents contradict the allegations of the amended complaint, the documents control and this Court need not accept as true the allegations in the amended complaint.").

Regardless of the creative terminology that Plaintiffs might coin for an agreement to split the remaining patent term and permit early generic entry, that agreement is a license and is a

lawful way to settle a patent case. *Actavis*, 133 S. Ct. at 2237; *End Payor*, 2015 WL 5610752, at *11. Plaintiffs' use of different labels for those settlement terms should not cause the Court to alter its conclusion that the settlements here fall squarely within the *Actavis* "safe harbor" for settlements that "'allow[] the generic manufacturer to enter the patentee's market prior to the patent's expiration, without the patentee paying the challenger to stay out prior to that point.'" *End Payor*, 2015 WL 5610752, at *11 (quoting *Actavis*, 133 S. Ct. at 2237).

B. Plaintiffs Have Not Alleged an Actionable "Reverse Payment"

1. The Accelerated Entry Provisions Are Procompetitive and Do Not Constitute "Reverse Payments"[4]

Like the plaintiffs in *End Payor*, Plaintiffs here allege that the accelerated-entry provisions, which accelerated each first filer's entry date if another generic ACTOS or ACTO*plus* met product entered the market earlier, were anticompetitive agreements "worth substantial sums." *See* Am. Compl. ¶¶ 256-258, 270. Plaintiffs call these provisions "coordination clauses," rather than "acceleration clauses" as the *End Payor* plaintiffs and the Court did. *E.g.*, *id.* ¶ 258. Of course, the analysis of these provisions is unaffected by Plaintiffs' effort to attach a pejorative (and incorrect) label to them.

The only reason offered by Plaintiffs for an alleged "deleterious impact on competition" caused by the accelerated-entry provisions with the first filers is that they supposedly "inhibited the interest of Teva . . . in continuing efforts to achieve early entry" and allegedly "create[d] a major disincentive" for other generics as well. *Id.* ¶¶ 257, 260, 264. These allegations have no more merit than they did in *End Payor*. First, as the Court recognized, "there is no plausible

[4] The accelerated entry provisions are the *only* supposed "payments" alleged against Mylan. Thus, if the Court determines that the accelerated-entry provisions do not constitute a reverse payment—or that their monetary value, if any, cannot be plausibly estimated—then Mylan must be dismissed from the case regardless of the Court's decision on the licensing terms reached with other Generic Defendants.

scenario in which another generic" besides the first filers "would have been entitled to earlier entry" on the facts alleged here. *End Payor*, 2015 WL 5610752, at *15. The Hatch-Waxman Act awarded 180 days of exclusivity to the first paragraph IV filers, and earlier entry by Teva or any hypothetical section viii ANDA filer was "foreclosed by the FDA's Citizen's Petition decision" prohibiting section-viii-only ANDAs. *Id.*

Second, "other generics," including Teva, "continued to pursue litigation regarding ACTOS" for months after Takeda's settlements with the first filers, and thus—contrary to Plaintiffs' claim—the subsequent generic filers were not in fact deterred. *Id.* Plaintiffs attempt to suggest otherwise by alleging that Takeda and Teva had been discussing settlement in the months following Takeda's settlements with the first filers. Am. Compl. ¶ 281 (Takeda and Teva "were talking" in April 2010 and "thought they could resolve the case"); *id.* ¶ 288 (Takeda and Teva "ha[d] begun exploring settlement" in August 2010). But an allegation that the parties had been exploring settlement hardly means that they had reached agreement or that Teva was not motivated to litigate. Indeed, Plaintiffs concede by their own allegations that the negotiations took several months—a fact that fatally undermines Plaintiffs' supposition that Teva lacked an incentive to obtain the best result for itself that it could. Plaintiffs' speculation about Teva's incentive also ignores the behavior of all the other later generic applicants, several of which did not even join the ACTOS patent litigation until *after* Takeda settled with Teva. *See id.* ¶¶ 227-228.

Third, "even if the Court were to credit Plaintiffs' speculation as to how other generics would have acted if not for the acceleration clauses," these provisions are nonetheless lawful because they merely "affect[] the date of entry into the market—a date that can be lawfully agreed upon." *End Payor*, 2015 WL 5610752, at *16. Thus, as the Court already determined,

they are not "reverse payments," but just a compromise on the date of entry—the kind of compromise *Actavis* shields from antitrust scrutiny and indeed encouraged as "bring[ing] about competition." *Actavis*, 133 S. Ct. at 2234.

Fourth, the Court has recognized that neither *Actavis* nor any other authority "demand[s] that the brand maximize competition" or maximize incentives for other generic companies to pursue patent challenges, so Plaintiffs cannot allege a cognizable claim based on the "mere possibility that the absence of an acceleration clause may result in more diverse generic competition." *End Payor*, 2015 WL 5610752, at *16; *see also Verizon Commc'ns, Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 415-16 (2004) ("The Sherman Act . . . does not give judges *carte blanche* to insist that a monopolist alter its way of doing business whenever some other approach might yield greater competition."); *La. Wholesale Drug Co. v. Shire LLC*, 929 F. Supp. 2d 256, 262 (S.D.N.Y. 2013) ("The mere fact that pricing for the public could have been lower under the terms of a particular settlement agreement does not mean that an antitrust violation results when that theoretical optimal result for consumers is not met."), *aff'd sub nom. In re Adderall XR Antitrust Litig.*, 754 F.3d 128 (2d Cir. 2014). Accordingly, the acceleration clauses are legitimate, procompetitive provisions for early entry that are shielded from antitrust scrutiny under *Actavis* and this Court's decision in *End Payor*.

2. Licenses for Ranbaxy and Actavis to Introduce an Additional Competing Product, and for Ranbaxy to Sell an Authorized Generic, Are Not "Reverse Payments"

Plaintiffs' allegations that Takeda's licenses to Ranbaxy and Actavis to market a generic version of ACTO*plus* met are "reverse payments" likewise rehashes the failed claims by the *End Payor* plaintiffs. The *End Payor* complaint alleged that Ranbaxy's and Actavis's receipt of licenses to market generic ACTO*plus* met as part of their settlements of their ACTOS patent litigation were "sweetheart deals" that "constituted illegal payments because neither Ranbaxy

nor Actavis had filed an ANDA for ACTO*plus* met and they could not have obtained the licenses as a result of the pending ACTOS litigation." *End Payor*, 2015 WL 5610752, at *16. Plaintiffs make the same criticism albeit with different labels. They say these same licenses were supposedly "higher-than-market" value, "of substantial value," and "could not have been obtained even if [Ranbaxy or Actavis] had won the ACTOS patent litigation." Am. Compl. ¶¶ 272-274.

The Court held in *End Payor* that those same factual allegations did not state a claim under *Actavis*: the "ACTO*plus* licenses merely allowed Actavis and Ranbaxy to enter the market earlier than they otherwise would have been permitted to do." *End Payor*, 2015 WL 5610752, at *17. The antitrust laws do not condemn licenses permitting generic products to enter the market early; such licenses, including those at issue here, are procompetitive and to be encouraged. *Actavis*, 133 S. Ct. at 2234. This Court thus properly held that "[b]oth the early-entry ACTOS and ACTO*plus* licenses were permissible settlement terms under *Actavis*, and the simultaneous grant of both does not render either license unlawful." *End Payor*, 2015 WL 5610752, at *17 (citing *FTC v. AbbVie Inc.*, 107 F. Supp. 3d 428, 436-37 (E.D. Pa. 2015)).

Plaintiffs also allege that the royalty rate paid by Ranbaxy to Takeda was 15 percentage points lower than the supposedly "customary" royalty rate. *See* Am. Compl. ¶ 272. But this is still not a "reverse payment" because all of the royalties flowed from Ranbaxy (the defendant) to Takeda (the plaintiff). *See, e.g.*, *End Payor*, 2015 WL 5610752, at *18 ("The only 'payments' provided for by the settlement consisted of 75 percent royalty payments from Teva *to* Takeda (*i.e.*, *not* reverse) for marketing its drugs as an authorized generic manufacturer. . . . [T]his type of early entry date settlement does not trigger antitrust scrutiny under *Actavis*."). A very similar "below market" royalty allegation made by the FTC was recently rejected in another case. The

court held that an alleged agreement to charge a generic manufacturer a supply price "that is well below what is customary in such situations" but above the brand manufacturer's cost was "not a reverse payment under *Actavis*" because the lower prices would benefit consumers. *AbbVie*, 107 F. Supp. 3d at 436. The same can be said here. Even if the royalty rate was below whatever Plaintiffs think is "customary," consumers would see the benefit of that reduced royalty rate.

For these reasons, the licenses to Ranbaxy and Actavis are not "reverse payments" and do not violate the antitrust laws.

3. Permitting Teva to Sell a Competing Product 180 Days Earlier Than It Otherwise Could Is Not a "Reverse Payment"

Again mirroring the *End Payor* allegations, Plaintiffs challenge Takeda's agreement to permit Teva to market authorized generics of both ACTOS and ACTO*plus* met, and thus compete along with Takeda and the other licensed generics. Am. Compl. ¶ 269. The Court correctly rejected this claim in the *End Payor* case. *See End Payor*, 2015 WL 5610752, at *17-19 (explaining that "[t]he only 'payments' provided for by the settlement consisted of 75 percent royalty payments from Teva *to* Takeda (*i.e.*, *not* reverse)" and that the terms of the settlement authorizing Teva to market generic ACTOS "stand in stark contrast to a true 'no authorized generic' pledge").

Plaintiffs here, like the *End Payor* plaintiffs, argue that the provision is a "reverse payment" because it "limit[ed] its authorized generic options to distributorships through the first wave generics and Teva, thus eliminating the launch of its own, independent authorized generic." Am. Compl. ¶ 269. But as the Court already recognized, no brand manufacturer is ever even "obligated as a matter of law" to license or market even one authorized generic, and "[i]n any event, Takeda *did* opt to license an authorized generic," namely Teva. *End Payor*, 2015 WL 5610752, at *18. As the Court previously concluded, "[t]hat Takeda opted to license one rather

than multiple authorized generics . . . does not render Takeda's agreement with Teva illegal." *Id.* at *19. Rather, "[t]he Teva agreement, like the [other] Generic Defendants' agreements, merely fixed early-entry dates for Teva to enter the ACTOS and ACTO*plus* markets" and "does not trigger antitrust scrutiny under *Actavis.*" *Id.* at *18.

Indeed, the settlement permitted Teva to enter "as an Authorized Generic at the same time as the first-filer Generic Defendants"—a time when Teva, as a second filer, otherwise had no ability to launch. *Id.* at *17. This provision indisputably "increased generic competition," by guaranteeing the possibility of four generics on the market during the 180-day exclusivity period for ACTOS, and two during the 180-day exclusivity period for ACTO*plus* met. *Id.* at *18. Given that Takeda *also* licensed Ranbaxy as an authorized generic for ACTOS, the settlement agreements resulted in more competition for consumers during the initial 180-day period than would have occurred without the settlements. Because the agreement itself was procompetitive, it makes no difference whether Plaintiffs can imagine a hypothetical alternative world that might have been even more procompetitive. *See id.* at *16.

Nor can Plaintiffs circumvent this Court's ruling in the *End Payor* case about the same settlement agreements by alleging that the Teva settlement included a "*de facto* payment from Takeda to Teva," namely, a royalty rate paid from Teva to Takeda that was supposedly lower than market rates "in these circumstances," which Plaintiffs allege should have been 90%. Am. Compl. ¶ 301. Plaintiffs' creative mischaracterization of the plain terms of the Teva settlement does not state a claim under *Actavis* as a matter of law. As the Court has already explained, the 75% royalty payment was made "from Teva *to* Takeda"—as royalties are traditionally paid from the accused infringer to the patent holder—and was thus "*not* reverse." *End Payor*, 2015 WL 5610752, at *18. *Actavis* made clear that there is nothing unlawful about traditional patent

settlements, including settlements with royalties from the generic company to patent holder. As the FTC conceded in *Actavis*, an early-entry license raises no antitrust concerns—even if it contains no royalty payment at all. *See* Reply Brief for the Petitioner at 12, *Actavis* (No. 12-416), 2013 WL 1099171.

As noted above, the court in *AbbVie* rejected the same theory of liability Plaintiffs now advance. There, the FTC challenged a settlement agreement between Abbott (the patent holder) and Teva (the generic company) that similarly included a royalty payment by Teva. *AbbVie*, 107 F. Supp. 3d at 437. Like Plaintiffs here, the FTC alleged that Abbott "charg[ed] a price that [was] well below what is customary in such situations" and thus that there was a "reverse payment because Teva is to pay Abbott significantly less money for [the product at issue] than the market calls for." *Id.* at 436. The court rejected that argument as a matter of law, finding "no basis in *Actavis*" for the claim. *Id.* As the court explained, "[c]onsideration or something of value invariably flows both ways as a result of any contract," but the Supreme Court in *Actavis* did not define an actionable reverse payment "so broadly as to include the opportunity afforded Teva to buy [the product at issue] and then sell it to the public in competition with Abbott." *Id.* It was simply not enough that the FTC believed that the patent holder "signed a bad deal for itself and a good deal for Teva" because whatever the royalty rate, an early-entry license agreement creates early entry for the benefit of consumers. *Id.*; *see also Trinko*, 540 U.S. at 415-16 (holding that an agreement does not become unlawful simply because a plaintiff can imagine better terms or an arrangement yielding more competition).

Actavis was concerned with "reverse payments" that were "large" and "unexplained." A contention that a *75%* royalty rate should have been a few percentage points higher does not satisfy this standard. If it did, then *every* settlement agreement would be subject to antitrust

scrutiny so long as any arguably more procompetitive settlement could be imagined. This Court rightly has already rejected such arguments as inconsistent with *Actavis*. *End Payor*, 2015 WL 5610752, at *29.

C. Even Assuming These Commonplace Licensing Terms Were Reverse Payments, Plaintiffs Still Do Not Properly Allege that the So-Called "Reverse Payments" Are "Large" or "Unexplained"

Plaintiffs' claims also fail because they lack plausible factual allegations that the supposed reverse payments are "large" and "unexplained." *See, e.g.*, *Actavis*, 133 S. Ct. at 2237 ("[A] reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects."); *End Payor*, 2015 WL 5610752, at *19 ("Plaintiffs' claims fail for the additional reason that they d[id] not plausibly allege that the payments were 'large' and 'unjustified' [as required by *Actavis*]."). As the Court has already held, it is not enough to "allege that the licensing terms in the settlements were of 'substantial value' and worth 'tens' and 'hundreds of millions' of dollars." *End Payor*, 2015 WL 5610752, at *19.

All Plaintiffs here allege is that the Generic Defendants made $350 million of "excess sales" because they "beat[] the other generics to the market." Am. Compl. ¶¶ 327-329. But that is pointedly *not* an allegation about the value of any purported reverse payment from Takeda to any Generic Defendant to stay out of the market. Nor is it the value of the acceleration clauses, the authorized generic licenses, or any other supposed "reverse payment" alleged by Plaintiffs. On the contrary, that is money the Generic Defendants allegedly made from *entering the market* and selling a *competing* version of the licensed product. Not only is this undeniably procompetitive, but it is precisely the type of settlement that the Supreme Court expressly approved in *Actavis*. *See Actavis*, 133 S. Ct. at 2234 ("[S]ettlement on terms permitting the patent challenger to enter the market before the patent expires would also bring about competition, again to the consumer's benefit.").

The reason why the Generic Defendants beat other generics to the market and supposedly earned $350 million is that Mylan, Ranbaxy, and Actavis were first filers entitled by law to a 180-day period of exclusivity. The FDA was prohibited by law from approving another ANDA for generic ACTOS before the 180-day period expired. 21 U.S.C. § 355(j)(5)(B)(iv). The 180-day exclusivity period was created by Hatch-Waxman—and is a "pro-consumer device" because it "induce[s] challenges to patents" that prospective generic manufacturers might otherwise find not worth the cost. *Teva Pharms. USA, Inc. v. Sebelius*, 595 F.3d 1303, 1318 (D.C. Cir. 2010). The first filers still would have had their 180 days of exclusivity even if they had received *earlier* dates of licensed entry as Plaintiffs allege they should have, or if there had been no settlements and the Generic Defendants won their patent litigations as Plaintiffs allege they would have.

Plaintiffs' contention that the 180-day exclusivity period was caused by Takeda's allegedly wrongful Orange Book listings is identical to one the Court dismissed in *End Payor*—and is addressed separately in Takeda's motion to dismiss Count 1. But, irrespective of whether the Orange Book listings were right or wrong, the relevant point is that the events giving rise to the first filers' 180-day exclusivity occurred years before the underlying patent infringement cases settled, as Plaintiffs seem to concede. *See* Am. Compl. ¶ 197 (alleging that by *filing* their ANDAs in 2003, Mylan, Ranbaxy, and Actavis "acquired . . . the right to be treated as 'first-to-file' ANDA applicants entitled to enjoy 180-day exclusivity"). The Orange Book listings, the 180-day exclusivity, the legal bar to FDA approval of other ANDAs before the 180-day period expired, and the supposed "excess sales" during the 180-day exclusivity period thus did not result from any alleged reverse payment in the settlements. Plaintiffs do not allege otherwise, nor could they. The Amended Complaint therefore does not plausibly allege that any "payments" were "large and unjustified," for the benefits at issue accrued years before the

settlement agreements were even signed, as a result of the Hatch-Waxman framework. *See End Payor*, 2015 WL 5610752, at *19.

For ACTO*plus* met, Plaintiffs' allegations that Takeda made "large" and "unjustified" settlement payments are likewise deficient. The allegation seems to be that during the first six months after the agreed-upon entry date, "only Mylan, Teva and Ranbaxy . . . were able to get into the ACTO*plus* met market, and they shared sales" of about "$17 million per month," which "would drop to about $14 million per month" when other generics launched. Am. Compl. ¶ 337.[5] Again, the reason why only Mylan and Teva were able to enter the market was that Mylan was entitled by law to 180 days of exclusivity, the FDA was prohibited by law from approving another ANDA for generic ACTO*plus* met before the 180-day period expired, and Teva was Takeda's authorized generic ACTO*plus* met distributor.[6] Allowing a period when some generic manufacturers can realize higher revenues than they otherwise would is precisely the point of the 180-day exclusivity period. *See Teva*, 595 F.3d at 1318 ("Congress deliberately created the 180-day exclusivity bonus"). Any supposedly "extra" revenue that Mylan and Teva earned during this period came from the way Hatch-Waxman was designed to (and did) operate, not as a result of any alleged reverse payment—and thus it does not support an antitrust claim.

II. Plaintiffs Have Failed to Allege Antitrust Injury Caused by the Settlement Agreements (Counts 2-6, 8)[7]

In *End Payor*, the Court held that the plaintiffs failed to state a claim for the additional, independent reason that the complaint did not allege any plausible, non-speculative theory of

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[5] As Plaintiffs know or should know, Ranbaxy has never filed an ANDA seeking to market a generic version of ACTO*plus* met. Thus, contrary to Plaintiffs' allegations, Ranbaxy was not marketing an ACTO*plus* met product during the 180-day exclusivity period or at any time thereafter.

[6] Plaintiffs concede that Mylan's 180-day exclusivity for generic ACTO*plus* met was entirely proper. Am. Compl. ¶ 17 n.3.

[7] There is no Count 7.

causation for the complained-of antitrust injury resulting from the settlement agreements. *End Payor*, 2015 WL 5610752, at *26-27. The theories of causation alleged by Plaintiffs here are materially identical and should be dismissed for the same reasons.

Plaintiffs' primary theory of competitive harm is that the Generic Defendants would have won the patent cases if they had not settled. *See, e.g.*, Am. Compl. ¶ 14 (the trial date for the ACTOS litigation "would have permitted Mylan, Ranbaxy, and/or Actavis to successfully conclude the patent litigation and enter the market on or about January 17, 2011, upon expiration of the '777 ACTOS Compound Patent").[8] This is the same theory of competitive harm advanced in the *End Payor* case, where the Court ruled that it was too speculative to form the basis for an antitrust claim. An antitrust complaint cannot go forward based on "theories requir[ing] the Court to assume that Takeda's patent claims were invalid and the infringement actions against the Defendants would have failed. Such assumptions regarding success at trial are generally rejected as unduly speculative unless the facts alleged establish a basis for concluding otherwise." *End Payor*, 2015 WL 5610752, at *27; *see also AbbVie*, 107 F. Supp. 3d at 437 ("allegations that the court would likely rule in favor of [the generic] is merely speculation"); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 201-02 (E.D.N.Y. 2003) (allegations relying on "the hope that [the generic manufacturer] would have prevailed in its [patent] suit" were "too speculative" and "insufficient to state a claim under the antitrust laws").

Plaintiffs' repeated allegations that Takeda's infringement claims were "weak" are simply repackaged versions of the *End Payor* plaintiffs' failed allegations that Takeda would have lost the patent infringement cases. Moreover, the only proffered bases for those allegations is that Takeda asserted its method-of-use claims on an induced-infringement theory and the

[8] Plaintiffs do not make a similar allegation for the ACTO*plus* met patent cases, but if they had, it would suffer from the same deficiencies as their allegations about the ACTOS patent cases.

Generic Defendants sought to file section viii statements regarding some of Takeda's patents. *See, e.g.*, Am. Compl. ¶ 201 ("Takeda's induced infringement claims, their only infringement claims, were weak."); *id.* ¶ 226 ("Takeda's ACTOS infringement claims [against Teva] under the '584 and '404 patents were based solely on the theory that the launch of an ACTOS generic would *induce* use of the product for combination use with metformin or insulin, and were therefore weak.").

The mere fact that Takeda relied on an inducement theory does not demonstrate "weakness." Judge Cote rejected the argument "that a generic drug manufacturer cannot induce infringement of combination-use patents." *End Payor*, 2015 WL 5610752, at *23 (quoting *Takeda*, 2007 WL 2936208, at *5). Inducement is a recognized theory of patent infringement, and induced infringement of pharmaceutical method-of-use claims have been asserted in Hatch-Waxman litigation. *See* Carrie Stewart Martin, *Proving Inducement of Infringement of Method-of-Use Patents in Hatch-Waxman Act Litigation: Are the Standards Realistic for the Pharmaceutical Industry?*, 32 AIPLA Q.J. 163, 172 (2004) ("[W]hen the patent covers a method of using a drug to treat a disease (a 'method-of-use' patent), the prescribing physicians and ingesting patients are the direct infringers. . . . [T]he inducement of infringement provision provides a way to hold the manufacturers of the infringing drug liable.").

Moreover, a section viii statement does not necessarily defeat an infringement claim. *See, e.g.*, *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1047, 1056-61 (Fed. Cir. 2010) (affirming district court's finding that patentee was entitled to preliminary injunction on induced-infringement claim, even though generic ANDA contained section viii statements). "A distributor of a drug may be liable for inducing infringement of a patent even though it has not acknowledged to the FDA that it intends to encourage the use of its product in a manner that

would conflict with a patent." *Takeda Chem. Indus., Ltd. v. Watson Pharms., Inc.*, 329 F. Supp. 2d 394, 401 (S.D.N.Y. 2004).

Plaintiffs also suggest that because Takeda's infringement claims were supposedly so likely to lose, the parties should have agreed to an entry date immediately after Takeda's '777 patent expired. *See, e.g.*, Am. Compl. ¶ 241 ("a reasonable, law-abiding brand company in the position of Takeda . . . would accept some negotiated entry date for ACTOS generics not long after the January 17, 2011 expiry of the '777 patent."); *id.* ¶¶ 245, 246, 247 (similar allegations about what a "reasonable, law-abiding generic company" would do).[9] But this theory just layers more speculation onto the already too-speculative idea that Takeda's patents were likely to lose. Plaintiffs are assuming not only that Takeda was likely to lose at trial, but also that Takeda believed it would likely lose at trial and would have capitulated as a result—equally speculative assumptions. Plaintiffs' guesses about what hypothetical companies "should" have done is inherently speculative and cannot support an antitrust claim.

III. Plaintiffs' Overarching Conspiracy Claim Fails as a Matter of Law (Counts 2-3)

Last, and again just like the *End Payor* plaintiffs, Plaintiffs assert conspiracy claims based on an alleged "overarching anticompetitive scheme . . . between Takeda, on the one hand, and Mylan, Actavis, Ranbaxy, and Teva on the other . . . to block and delay market entry of AB-rated generic versions of ACTOS and ACTO*plus* met." Am. Compl. ¶ 431; *see also id.* ¶ 438.

As explained in *End Payor*, "[t]he existence of an agreement" shared among all Defendants "is a legal conclusion; a mere conclusory allegation that Defendants agreed to enter into unlawful settlements without supporting factual allegations is insufficient to state a claim for relief." *End Payor*, 2015 WL 5610752, at *23. To survive dismissal, Plaintiffs must "'allege

[9] Again, Plaintiffs do not make a similar allegation about the ACTO*plus* met settlement.

enough facts to support the inference that a conspiracy actually existed,'" which they may do "in one of two ways": by alleging "direct evidence that defendants entered into an agreement in violation of the antitrust laws," or by alleging "circumstantial facts supporting the inference that a conspiracy existed." *Id.* at *23-24 (quoting *Mayor & City Council of Baltimore v. Citigroup, Inc.*, 709 F.3d 129, 135-36 (2d Cir. 2013)). Plaintiffs have done neither. Indeed, the facts alleged in support of the conspiracy claims are materially indistinguishable from those alleged and rejected in the *End Payor* case.

A. The Amended Complaint Does Not Plausibly Allege Direct Evidence of a Conspiracy

Like the complaint in the *End Payor* case, the Amended Complaint here does not allege any direct evidence that Defendants entered into an illegal agreement. It contains no more than conclusory allegations that Takeda and the first filers entered into a "March 2010 pact" that was an "orchestrated . . . group deal in which all three of the [first filers] settled litigation at the same time, in a coordinated way, and, essentially, as part of a single transaction." Am. Compl. ¶ 248. In contrast to this spare pleading, "a Sherman Act § 1 complaint premised on direct evidence of an agreement requires 'time, place, or person' allegations regarding the claimed illegal agreement." *Rochester Drug Co-op., Inc. v. Biogen Idec U.S. Corp.*, --- F. Supp. 3d ----, 2015 WL 5474666, at *4 n.2 (W.D.N.Y. Sept. 18, 2015); *see also Twombly*, 550 U.S. at 565 n.10 (dismissing an antitrust conspiracy case in which "the pleadings mentioned no specific time, place, or person involved in the alleged conspiracies"). No such "time, place, or person" allegations are present here. Most obviously, there are no factual allegations of agreements among the various Generic Defendants.

B. The Amended Complaint Does Not Plausibly Allege Circumstantial Evidence of a Conspiracy

The Amended Complaint also fails to allege a conspiracy circumstantially. Allegations of parallel conduct, even conscious parallel conduct, do not create a plausible inference of an illegal conspiracy—and for that reason were rejected in the *End Payor* case. *See End Payor*, 2015 WL 5610752, at *24 ("parallel conduct alone is generally insufficient to defeat a motion to dismiss"); *see also Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 227 (1993) ("conscious parallelism" is "not in itself unlawful"). To survive dismissal, "[P]laintiffs must also allege the existence of other circumstances, typically called 'plus factors,'" such as "a common motive to conspire, evidence establishing that the conduct was against the economic self-interest of the alleged conspirators, and frequent interfirm communications." *End Payor*, 2015 WL 5610752, at *24. They have not done so.

To begin with, Plaintiffs cannot allege parallel conduct among all the Generic Defendants, or even all the ACTOS first filers. Mylan, Ranbaxy, and Actavis each settled its respective ACTOS patent case in March 2010, whereas Teva did not settle until nine months later. *Compare id.* at *6 (describing the Mylan, Ranbaxy, and Actavis ACTOS settlements), *with id.* at *8 (describing the Teva settlement). Each first filer also received different rights under its respective settlement. For example, Ranbaxy received an option to purchase supply of authorized generic ACTOS product from Takeda, but Mylan and Actavis did not. *Compare* Ex. 1, § 3.6 (describing Ranbaxy's supply option), *with* Ex. 2 at 10-11 (no similar option for Mylan), *and* Ex. 4 at 8-12 (no similar option for Actavis). Actavis received the right to take orders in preparation for its commercial launch of generic ACTOS thirty days before its scheduled launch, but Mylan and Ranbaxy did not. *Compare* Ex. 4, § 3.4, *with* Ex. 1 at 7-10 (no similar right for Ranbaxy), *and* Ex. 2 at 7-11 (no similar right for Mylan). Takeda assured Mylan that it would

not make any arguments to the FDA that might interfere with Mylan's launch of generic ACTOS, but Takeda did not give Ranbaxy or Actavis that assurance. *Compare* Ex. 2, § 3.5 (Takeda's assurance to Mylan), *with* Ex. 1 at 7-10 (no similar promise to Ranbaxy), *and* Ex. 4 at 8-12 (no similar promise to Actavis).

Plaintiffs' claims also fail because the Amended Complaint does not contain any well-pleaded allegations about any plus factors. Like the *End Payor* plaintiffs, Plaintiffs allege no facts establishing "that the Generic Defendants communicated with each other in advance of entering the settlements, or that the settlements were negotiated together." *End Payor*, 2015 WL 5610752, at *25.

Plaintiffs attempt to allege that the settlements were contrary to the Generic Defendants' self-interest, reasoning that if the Generic Defendants were "[a]cting in their own, independent economic interest," they "would each (separately) seek from Takeda an agreed entry date on or shortly after January 17, 2011." *E.g.*, Am. Compl. ¶ 246. But these allegations about the Generic Defendants' self-interest are speculative conclusions, not facts, and thus the Court need not credit them. *See End Payor*, 2015 WL 5610752, at *25 (plaintiffs must allege a "factual basis from which to infer that, on balance, the agreements were against the Defendants' self-interest"). Instead, the Court may "draw on its judicial experience and common sense" in assessing the allegations. *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009).

Here, the conclusory allegations make no sense. First, Plaintiffs cannot and do not explain why the three generic companies supposedly acting together would have been willing to accept a later entry date than the generic companies negotiating on their own. Second, regardless of the entry date the Generic Defendants might have *sought*, any settlement obviously would have required the consent of Takeda. Plaintiffs' only basis to suggest that Takeda would have

agreed to earlier entry is the supposed "(limited) merits" of its patents. Am. Compl. ¶¶ 240-241. The Court, however, already held that alleged weakness of patent litigation is too speculative a basis for permitting burdensome and expensive antitrust litigation to proceed. *See End Payor*, 2015 WL 5610752, at *25 ("[T]here is no factual basis from which to infer that, on balance, the agreements were against the Defendants' self-interest. Plaintiffs' argument to the contrary requires the Court to assume that [the Generic] Defendants would have fared better had they proceeded to trial, and that assumption is pure speculation.").

Finally, and perhaps most importantly, Plaintiffs have no basis to conclude that "[n]one of the [first filers] would have agreed to the late entry dates for ACTOS and ACTOplus entry without knowing that their generic competitors were getting the same deal." Am. Compl. ¶ 252. The accelerated-entry clauses themselves make Plaintiffs' allegations implausible. If (hypothetically) one of the first filers had negotiated a license to launch generic ACTOS before August 17, 2012, the others would have been able to benefit from that earlier date under the very acceleration clauses that Plaintiffs challenge. Common sense demonstrates that no generic company had reason to demand that all three have the same agreed-upon entry date. The *King Drug* court explained this very point: "with the presence of the contingent launch provisions, there was nothing to gain from conspiring with the other Generic Defendants to fix the [settlement agreements'] entry date."[10] *King Drug*, 2014 WL 2813312, at *13.

Far from being contrary to each Generic Defendant's independent self-interest, and as a the Court already recognized, the settlements offered both "an end to costly litigation" and "an

[10] In *King Drug*, the court used the term "contingent launch provisions" to refer to the same types of provisions that in *End Payor* were called "accelerated-entry provisions" and in this case Plaintiffs have labeled "coordinated entry provisions." *King Drug*, 2014 WL 2813312, at *3 (explaining that the contingent launch provisions were contractual clauses that "permitted each settling Generic to sell its product prior to [the agreed-upon entry date] if any other company brought a generic version of Provigil to market").

assurance that each Generic Defendant would not be disadvantaged regarding [generic entry].” *End Payor*, 2015 WL 5610752, at *25 (alteration in original) (quoting *King Drug*, 2014 WL 2813312, at *12).

IV. Plaintiffs Should Be Denied Leave to Amend

Plaintiffs waited to file their original complaint until after they had the benefit of the *End Payor* complaints, briefing on the motions to dismiss in the *End Payor* case, and oral argument on those motions. They then amended their complaint (a second time) after receiving the Court’s detailed opinion in the *End Payor* case. Having been unable to state a valid claim under these circumstances, Plaintiffs should be denied further leave to amend.

CONCLUSION

For the foregoing reasons, Defendants respectfully request that the Court dismiss the claims against them with prejudice.

Respectfully submitted,

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